510(k) Summary

AUG 18 2011

Enter your 510(k) Summary or Statement.

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K110296 .

Submission correspondent:

Dr Claire Dora
RA Manager
Axis-Shield Diagnostics Ltd.
The Technology Park
Dundee DD2 1XA, UK

Device Name: Axis-Shield anti-CCP

Reagents:

Classification Name: Antibodies, ANTI-CYCLIC CITRULLINATED PEPTIDE (CCP)
Trade Name: Axis-Shield Anti-CCP
Common Name: Anti-CCP test
Governing Regulation: 866.5775
Device Classification: Class II
Classification Panel: Immunology (82)
Product Code: NHX, Antibodies, ANTI-CYCLIC CITRULLINATED PEPTIDE (CCP)

Legally marketed device to which equivalency is claimed:

DIASTAT™ Anti-CCP Assay (K023285)

Intended Use of Device:

The Axis-Shield Anti-CCP test is a semi-quantitative/qualitative enzyme-linked immunosorbent assay (ELISA) for the detection of the IgG class of autoantibodies specific to cyclic citrullinated peptide (CCP) in human serum (including Serum Separator Tubes) or plasma (EDTA, lithium heparin, or sodium citrate). Detection of anti-CCP antibodies is used as an aid in the diagnosis of Rheumatoid Arthritis (RA), and should be used in conjunction with other clinical information. Autoantibody levels represent one parameter in a multi-criterion diagnostic process, encompassing both clinical and laboratory-based assessments.
For in vitro diagnostic use.

Indication(s) of Use:

Same as Intended Use

Description of Device:

The Axis-Shield Anti-CCP device contains the following components:
a microtitre plate with 8 x 12-well breakapart strips coated with purified synthetic cyclic citrullinated peptide, in a resealable foil pack with desiccant; ready to use calibrators (diluent with or without IgG antibodies against CCP2); positive and negative assay controls (human plasma with or without IgG antibodies against CCP); ready-to-use reference control; goat anti-human IgG horseradish peroxidase conjugate; TMB substrate; sample diluent (5x) wash buffer (10x); ready-to-use stop solution.

Principle of the Assay:

The wells of the microtitre strips are coated with a highly purified synthetic cyclic citrullinated peptide containing modified arginine residues. During the first incubation, specific autoantibodies in diluted serum or plasma bind to the antigen-coated surface. The wells are then washed to remove unbound components. In the second incubation, the Conjugate, an enzyme-labelled polyclonal antibody to human IgG, binds any surface-bound autoantibodies. After further washing, specific autoantibodies are traced by incubation with the Substrate. Addition of Stop Solution terminates the reaction, resulting in a coloured end-product. The amount of Conjugate bound is measured in absorbance units. In the qualitative protocol, the amount of Conjugate bound by the sample is compared with that bound by the Reference Control. In the semi-quantitative protocol, the concentration of anti-CCP autoantibody can be estimated by interpolation from a dose-response curve based on Calibrators.

Comparison of Technological Characteristics:

The Axis-Shield Anti-CCP device is a semi-quantitative/qualitative enzyme-linked immunosorbent assay.

The predicate device, DIASTAT™ Anti-CCP is also an enzyme-linked immunosorbent assay.

Summary of Non-Clinical Performance:

The Axis-Shield anti-CCP and DIASTAT™ Anti-CCP tests are enzyme-linked immunosorbent assays. The Axis-Shield Anti-CCP assay demonstrated substantially equivalent performance to the DIASTAT™ anti-CCP assay in terms of matrix comparison and assay interference as demonstrated by the non-clinical performance data included in this 510(k) submission.

Summary of Clinical Performance:

The Axis-Shield Anti-CCP assay demonstrated substantially equivalent clinical performance to the DIASTAT™ anti-CCP assay as indicated by a method comparison and concordance analysis, whereby 99 % concordance for all samples tested (n= 514) was demonstrated.

A Receiver Operator Characteristic (ROC) curve analysis (using the suggested cut-off of 5.0 U/mL) determined that the area under the curve (AUC) for the Axis-Shield anti-CCP assay was 0.910 (95% Confidence Interval: 0.881 to 0.940) and 0.903 (95% Confidence Interval: 0.871 to 0.934) for the DIASTAT™ anti-CCP assay. This analysis indicates that the two assays are comparable with respect to cut-off and clinical differentiation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Axis-Shield Diagnostics Limited
c/o Dr. Claire I. Dora
Regulatory Affairs Manager
The Technology Park, Luna Place
Dundee, Scotland
United Kingdom DD2 1XA

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Re: k110296
Trade name: Axis-Shield Anti-CCP
Regulation Number: 21 CFR §866.5775
Regulation Name: Rheumatoid factor immunological test system
Regulatory Class: Class II
Product Code: NHX
Dated: July 19, 2011
Received: July 21, 2011

Dear Dr. Dora:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of

substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Reena Philip

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K110296

Device Name: Axis-Shield anti-CCP

Indication For Use:

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For in vitro diagnostic use.

Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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